UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

Moose Jooce, et al., Plaintiffs, v. **Food and Drug Administration**, et al., Defendants.	No. 18-cv-203 CRC Hon. Christopher R. Cooper United States District Judge
Rave Salon, Inc., d/b/a Joosie Vapes, Plaintiff, v. **Food and Drug Administration**, et al., Defendants.	No. 18-cv-1615 CRC
Jen Hoban d/b/a Masterpiece Vapors, et al., Plaintiffs, v. **Food and Drug Administration**, et al., Defendants.	No. 19-cv-372 CRC

REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN FURTHER SUPPORT OF GOVERNMENT'S CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

Table of Contents

Table of Authorities

Cases

Constitutional Provisions, Statutes, Regulations, and Rules

Other Authorities

I. Introduction

The plaintiffs' reply exposes the remarkable ramifications of their Appointments Clause theory. In their view, Appointments Clause challenges cannot be forfeited — so they can be raised years later to invalidate settled agency rules and regulations. Nor can Appointments Clause defects be readily cured in the plaintiffs' eyes — so ratification of an agency rule demands a re-do of all the procedures required to make that rule anew. And on the merits, the plaintiffs' Appointments Clause theory would not only invalidate the entire FDA deeming rule and short-circuit the FDA's regulation of e-cigarettes, which are now used by kids at epidemic levels. It would also bar any career Senior Executive Service member from serving as an inferior officer anywhere in the federal government — calling into question the constitutionality of countless agency actions over the past four decades.

The plaintiffs' theory, however, is not the law. It is well established that Appointments Clause challenges can be forfeited when the challenger is on notice of the alleged infirmity yet fails to raise it with the agency. The plaintiffs did so here by failing to raise any challenge to Associate Commissioner Kux's authority to sign the final deeming rule during the rulemaking comment period.

It is likewise well established that Appointments Clause defects can be cured when a properly appointed official has the power to take the action in question and ratifies that earlier action. Two FDA Commissioners whose appointment and authority is unquestioned did so here. The plaintiffs' challenge to Commissioner Califf's ratification as perfunctory violates the basic principle that ratifications are to be taken at face value. And the plaintiffs' challenge to Commissioner Gottlieb's ratification for failing to address studies released after the deeming rule mistakes an Administrative

Procedure Act issue for an Appointments Clause issue. Nor does the "voluntary cessation" exception to mootness keep the plaintiffs' claims alive, given that ratification resolves an Appointments Clause claim on the merits.

Finally, even if not forfeited or cured, the Appointments Clause claim fails on the merits because the deeming rule was issued by a duly appointed inferior officer. Taken together, the considerable direction, supervision, and removal authority to which the Associate Commissioner for Policy is subject under existing delegations of authority — plus her superiors' ability to rescind that delegated authority to exert even more control — make her an inferior officer. And Ms. Kux was appointed to that position "by Law" under the HHS Secretary's broad statutory authority to manage FDA operations, enlist subordinates, and delegate functions to those subordinates.

The government's summary judgment motion should be granted.

II. Argument

A. The Appointments Clause challenge has been forfeited

The government explained that the plaintiffs forfeited their Appointments Clause challenge by failing to raise it during the rulemaking proceedings. Gov't Br. at 18–20, ECF No. 28-1.[1] In response, the plaintiffs do not dispute that neither they nor anyone else questioned Associate Commissioner Kux's authority in the more than 135,000 comments submitted during the rulemaking proceedings.

Instead, the plaintiffs contend that Appointments Clause challenges are structural and thus cannot be forfeited. Pls.' Reply at 28, ECF No. 30. But the D.C.

---

[1] For the Court's convenience, citations to docket entries and legal authorities in the PDF version of this brief are linked to the cited authorities in ECF and Westlaw, respectively.

Circuit has held that Appointments Clause challenges are subject to "normal forfeiture rule[s]." *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 574 F.3d 748, 756 (D.C. Cir. 2009) (per curiam) (*Intercollegiate I*) (holding that Appointments Clause challenge was forfeited). Under those rules, "issues not raised in comments before the agency [during rulemaking proceedings] are waived." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002). And although the Court retains discretion to consider untimely challenges in "rare cases," the plaintiffs have offered no compelling reason to do so here. *Intercollegiate I*, 574 F.3d at 756 (citation omitted).

The plaintiffs contend they could not have known during the rulemaking comment period that Associate Commissioner Kux would sign the final deeming rule. Pls.' Reply at 28. But the forfeiture rule does not require a party to know with 100% certainty that an issue will arise; instead, the rule applies as long as "the party had *notice* of the issue." *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079 (D.C. Cir. 2009) (emphasis added); *accord Estes v. U.S. Dep't of Treasury*, 219 F. Supp. 3d 17, 37 (D.D.C. 2016) (Cooper, J.) (forfeiture rule does not apply when party "had no way to raise [an] argument") (citation omitted) (brackets in original). Here, the plaintiffs do not dispute that, before Associate Commissioner Kux signed the final deeming rule, she also signed the proposed deeming rule, a notice extending the comment period, and hundreds of other FDA rules — giving the plaintiffs fair notice of the alleged infirmity.

The plaintiffs also contend that they are not equipped to raise complex constitutional arguments during rulemaking proceedings. Pls.' Reply at 29. Forfeiture rules, however, apply not just to supposedly "quotidian issues" like the "operational or economic impact to a business," Pls.' Reply at 29, but also to constitutional issues. *See, e.g., Baltimore v. Clinton*, 900 F. Supp. 2d 21, 36 (D.D.C. 2012). And contrary to the

plaintiffs' suggestion, avoiding forfeiture does not require extensive legal argument. Instead, it requires only that an issue be raised with enough specificity "to give the [agency] a *fair opportunity* to pass on a legal or factual argument." *Nat'l Ass'n of Mfrs. v. U.S. Dep't of Interior*, 134 F.3d 1095, 1111 (D.C. Cir. 1998) (citation omitted) (brackets and emphasis in original). Here, neither the plaintiffs nor anyone else questioned Associate Commissioner Kux's authority to sign the deeming rule — depriving the FDA of any opportunity to address the issue before it promulgated the final rule. "Simple fairness ... requires as a general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice." *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952). By failing to make such an objection during the rulemaking process, the plaintiffs forfeited their Appointments Clause challenge.

B. Ratification has cured any Appointments Clause issue

The government also explained that any Appointments Clause problem was cured when the deeming rule was later ratified by either of two FDA Commissioners nominated by the President and confirmed by the Senate. Gov't Br. at 20–28. In response, the plaintiffs do not question the appointment or authority of either Commissioner. Nor do they dispute that the burden is on them to show some continuing prejudice from the alleged Appointments Clause violation. Instead, they contend that both ratifications were ineffective and that the "voluntary cessation" exception to mootness applies. Those contentions, however, fail to save the Appointments Clause claim.

1. Commissioner Califf's 2016 ratification was effective

The plaintiffs challenge the effectiveness of Commissioner Califf's September 2016 ratification, contending that it was perfunctory and did not specifically mention the deeming rule. Pls.' Reply at 18–19. They do not dispute, however, that Commissioner Califf was well aware of the deeming rule and made contemporaneous public statements in support of the rule. APP 226. And under the governing legal standard, ratifications must be "take[n] ... at face value" — even those that seem to be "nothing more than a 'rubberstamp'" of the prior decision. *FEC v. Legi-Tech, Inc.*, 75 F.3d 704, 709 (D.C. Cir. 1996). Applying that standard, courts have upheld "blanket" ratifications approving all actions taken during a particular period without specifically mentioning the challenged action — like Commissioner Califf's 2016 ratification. *E.g.*, *State Nat'l Bank of Big Spring v. Lew*, 197 F. Supp. 3d 177, 180, 184–186 (D.D.C. 2016) ("I hereby affirm and ratify any and all actions I took during that period."); *Advanced Disposal Servs. E., Inc. v. NLRB*, 820 F.3d 592, 602–606 (3d Cir. 2016) ("[We] confirm, adopt, and ratify *nunc pro tunc* all administrative, personnel, and procurement matters approved by the Board or taken by or on behalf of the Board from January 4, 2012, to August 5, 2013, inclusive.").

The plaintiffs also contend that Commissioner Califf's 2016 ratification is best read to cover only actions lacking proper *statutory* or *administrative* authority, not actions lacking proper *constitutional* authority. Pls.' Reply at 18–19. That is not a fair reading of the ratification — let alone one that takes the ratification "at face value." *Legi-Tech*, 75 F.3d at 709. Commissioner Califf's ratification says: "I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation." APP 144.

By its terms, that ratification covers all actions taken under the prior delegation of authority, regardless of the supposed deficiency. And the plaintiffs do not dispute that Associate Commissioner Kux's signing of the deeming rule in May 2016 "involved the exercise of the authorities delegated herein prior to the effective date of this delegation."

It is undisputed that Dr. Califf was a properly appointed FDA Commissioner with the power to issue the deeming rule. *See Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 796 F.3d 111, 117 (D.C. Cir. 2015) (*Intercollegiate III*). He ratified it in September 2016 — taking responsibility for the deeming rule and curing any Appointments Clause problem. That ratification alone conclusively resolves the Appointments Clause claim.

2. Commissioner Gottlieb's 2019 ratification was effective

The plaintiffs also challenge Commissioner Gottlieb's April 2019 ratification on the ground that it failed to address studies released after the deeming rule's issuance in May 2016. Pls.' Reply at 19–22. That contention mistakes an APA issue for an Appointments Clause issue, as the government explained. Gov't Br. at 23–25. "There is no Appointments Clause problem in limiting [a party] to the evidence ... submitted to the [allegedly improperly appointed decisionmaker]." *Intercollegiate III*, 796 F.3d at 122. Instead, the only question under the Appointments Clause is whether "a properly appointed official has the power to conduct an independent evaluation of the merits and does so." *Id.* at 117. When Dr. Gottlieb ratified the deeming rule in April 2019, he was a properly appointed FDA Commissioner with the power to issue FDA rules like the deeming rule. And the plaintiffs do not dispute that his ratification constituted an independent evaluation of the merits of the deeming rule.

The plaintiffs nevertheless contend that Commissioner Gottlieb lacked the power to issue the deeming rule in April 2019 without addressing the intervening studies because doing so would be arbitrary and capricious under the APA. Pls.' Reply at 19–20. But the D.C. Circuit has explained the logical flaw in that argument: A ratification "is not ... the '*basis*' for" the original agency action, but rather "an affirmation of the [prior] decision" that "ha[s] the legal consequence of ratifying" it. *Doolin Sec. Sav. Bank, F.S.B. v. Office of Thrift Supervision*, 139 F.3d 203, 213 n.11 (D.C. Cir. 1998) (emphasis added), *superseded by statute on other grounds*, Federal Vacancies Reform Act of 1998, Pub. L. No. 105-277, 122 Stat. 2681. Because it does not purport to be the "basis" for the original action, a ratification need not comply with the same requirements as if the original action were being taken from scratch. *Id.* Commissioner Gottlieb's ratification thus did not need to address the intervening studies identified by the plaintiffs.

At bottom, the plaintiffs' challenge to Commissioner Gottlieb's power in April 2019 obscures the difference between (a) lacking any authority to take an action at the time of ratification, and (b) having to comply with certain procedures to take that action anew. The standard for effective ratification is concerned only with the former — like the Solicitor General in *FEC v. NRA Political Victory Fund* who lacked any authority to file a certiorari petition after a jurisdictional deadline and thus could not ratify an earlier petition. 513 U.S. 88, 98–99 (1994). By contrast, the latter is irrelevant to the ratification question; a ratification is effective even if it did not "involve[] a repetition of the procedures initially followed."[2] *State Nat'l Bank*, 197 F. Supp. 3d at 184. Thus, for example:

[2] The plaintiffs contend that they do not seek to force the FDA to repeat *all* APA rulemaking requirements. Pls.' Reply at 22. But their theory applies with equal force to

- A ratification of an informal rule is effective despite not being published in the Federal Register — even though the APA generally requires such rules to be published in the Federal Register. *Alfa Int'l Seafood v. Ross*, 264 F. Supp. 3d 23, 46 (D.D.C. 2017); *Huntco Pawn Holdings, LLC v. U.S. Dep't of Defense*, 240 F. Supp. 3d 206, 232 (D.D.C. 2016).

- A ratification of an informal rule is effective despite not repeating notice-and-comment rulemaking procedures — even though the APA generally requires such rules to undergo those procedures. *State Nat'l Bank*, 197 F. Supp. 3d at 184.

- A ratification of an FEC enforcement action is effective without an investigation and deliberation — even though those procedures are required to bring an enforcement action in the first place. *Legi-Tech*, 75 F.3d at 708.

- A ratification of administrative enforcement proceedings is effective without a signed notice containing the charges — even though such a notice of charges is generally required to commence administrative enforcement proceedings. *Doolin*, 139 F.3d at 213–214.

- A ratification of a copyright royalty rate adjudication is effective without a new evidentiary hearing — even though an evidentiary hearing is generally required in copyright royalty rate proceedings. *Intercollegiate III*, 796 F.3d at 120.

Here, likewise, Commissioner Gottlieb's April 2019 ratification of the deeming rule was effective even if issuing the rule anew might have required him to address the intervening studies. All that matters is that he had the power to conduct an independent evaluation of the rule and did so. *See id.* at 117.

---

every APA rulemaking requirement. For example, under their theory — under which the ratification "must be assessed as if the 2016 final rulemaking had never happened," *id.* — Commissioner Gottlieb could not issue the deeming rule in April 2019 without following notice-and-comment rulemaking procedures, so his ratification (which did not repeat those procedures) was ineffective. That argument, however, has been repeatedly rejected by the D.C. Circuit. *See State Nat'l Bank*, 197 F. Supp. 3d at 184 (citing cases).

Regardless, even under the plaintiffs' theory, Commissioner Gottlieb had no obligation to address the intervening studies. Contrary to the plaintiffs' contention, the APA does not require that, before issuing a final rule, agencies must address all "substantial developments," wherever they might be found. Pls.' Reply at 19–20. Instead, agencies need only "consider and respond to significant comments *received during the period for public comment*." *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) (emphasis added). Comments "raised at the wrong time or in the wrong docket will not do" because "notice does not operate by osmosis." *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001). Thus, even if this APA principle applied to ratifications, it would not have required Commissioner Gottlieb to consider and respond to studies that he supposedly learned about in a different context some four years after the deeming rule comment period had closed and some two years after the final deeming rule had been issued.[3] Pls.' Reply at 20–21. His ratification was therefore effective even under the plaintiffs' theory.

In all events, even if the subsequent studies had been properly presented to the agency, they would not have required a response. Those studies reported similar information as earlier studies presented to and considered by the FDA, as the government explained. Gov't Br. at 25–26. Comments presented to an agency do not rise to the level of "significant" — and thus do not require a response under the APA — unless "if adopted, [they] would require a change in the agency's proposed rule." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977). Here, as Commissioner

[3] This rule creates no catch-22, contrary to the plaintiffs' contention. Pls.' Reply at 21. The APA provides a straightforward procedure for presenting the subsequent studies, as the government explained. Gov't Br. at 24.

Gottlieb recently explained, even if e-cigarettes are potentially an adult "off-ramp" from traditional cigarette use (as the plaintiffs claim these later studies show), the deeming rule is still justified "to close the on-ramp that has resulted in the widespread and increasingly frequent use of e-cigarettes by teens." Alex M. Azar & Scott Gottlieb, *The Future of E-Cigarettes Depends on the Industry's Willingness to Protect Teens*, Wash. Post, Mar. 20, 2019, https://www.washingtonpost.com/opinions/2019/03/19/future-e-cigarettes-depends-industrys-willingness-protect-teens/.

The later studies identified by the plaintiffs therefore do not undermine the effectiveness of Commissioner Gottlieb's 2019 ratification, which cured any Appointments Clause problem with the deeming rule.[4]

---

[4] The plaintiffs also contend that Commissioner Gottlieb's ratification was ineffective because re-doing the full-blown notice-and-comment process today might yield a different rule, as supposedly evidenced by the FDA's subsequent industry guidance deferring enforcement of certain provisions. Pls.' Reply at 25–27. But that proposed remedy has never been required for an alleged Appointments Clause violation during rulemaking, and even the Supreme Court in *Lucia v. SEC* made clear that its prescribed remedy of a "new hearing" was limited to adjudications. 138 S. Ct. 2044, 2055 (2018).

Also, the supposed prejudice identified by the plaintiffs is not attributable to the alleged *Appointments Clause violation* and thus does not render the ratification ineffective, as the Third Circuit has recognized in an analogous context. *See Advanced Disposal*, 820 F.3d at 605. Here, as there, the plaintiffs "do[] not argue that [the allegedly] improper appointment in any way affected [the properly appointed decisionmaker's ratification] and thus prejudiced" the plaintiffs. *Id.* Instead, their focus on factors *besides* the allegedly improper appointment makes it "clear that what [they] *really* want[] is a second shot at" getting a different result in the rulemaking process — which fails to establish prejudice from the alleged Appointments Clause violation. *Id.* (citing *Doolin*, 139 F.3d at 214).

In all events, the industry guidance provides no basis to think that the FDA would issue a different rule today, as the government explained. Gov't Br. at 26 n.5. Nor is the plaintiffs' challenge to Commissioner Gottlieb's ratification helped by another district court's vacatur of certain compliance-policy changes in *American Academy of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 498 (D. Md. May 15, 2019). In its subsequent remedies decision, the court clarified that it "did not suggest that the FDA needed to

3. The voluntary cessation exception to mootness does not apply because ratification resolves an Appointments Clause claim on the merits

The government explained that ratification resolves any Appointments Clause defect on the merits, not on mootness grounds, as the D.C. Circuit has "repeatedly held," so the voluntary cessation exception to mootness does not apply. Gov't Br. at 27 (quoting *Guedes v. ATF*, 920 F.3d 1, 13 (D.C. Cir. 2019)).

In response, the plaintiffs contend that *Guedes* did not actually decide whether ratification is a merits or mootness issue. Pls.' Reply at 22–23. That is not a fair reading of the case, which concluded that an attempt to invoke the voluntary cessation exception to save an Appointments Clause claim "fails because ratification is generally treated as a disposition on the legal merits of the appointments challenge and, in any event, no mootness exception applies in this case."[5] 920 F.3d at 12. And even if *Guedes* had not decided the question, the plaintiffs do not even attempt to address the four other cases in which the D.C. Circuit "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting a claim, resolves the claim on the merits." *Id.* at 13 (citing *Wilkes-Barre Hosp. Co. v. NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017); *Intercollegiate III*, 796 F.3d at 119 n.3; *Doolin*, 139 F.3d at 205,

---

issue a formal regulation in lieu of guidance" — thus undermining the plaintiffs' suggestion that those compliance-policy changes would be incorporated into the deeming rule if it were issued anew today. *Am. Acad. of Pediatrics v. FDA*, No. 18-cv-883, 2019 WL 3067492, at *1 n.4 (D. Md. July 12, 2019); Pls.' Reply at 27.

[5] This *alternative* holding that the voluntary cessation exception did not apply "in any event" — far from helping the plaintiffs — is fatal here because those grounds apply with equal force in this case, as the government explained. Gov't Br. at 27.

207, 212–214; *Legi-Tech*, 75 F.3d at 708 n.5). Those holdings establish that either FDA Commissioner's ratification resolves the Appointments Clause claim on the merits.

Nor are the plaintiffs' attempts to distinguish *Guedes* persuasive. Pls.' Reply at 22–25. They contend that *Guedes* involved a defense to an individual enforcement action, not a pre-enforcement challenge to an agency rule. Pls.' Reply at 22–23. But they fail to explain why that difference should matter. The reason ratification resolves the merits of a claim is that it is "analogous to harmless-error analysis" — which applies with full force to rulemaking and adjudication alike, as *Guedes* explained. 920 F.3d at 13. Here, as in *Guedes*, the ratifications "purge[] any residual taint or prejudice left over from the allegedly invalid appointment" because two properly appointed FDA Commissioners have taken responsibility for the deeming rule.[6] *Id*.

Finally, the plaintiffs contend that the ratifications do not cure the Appointments Clause problem because they do not prevent the Associate Commissioner for Policy from signing *future* FDA rules.[7] Pls.' Reply at 23–25. But the plaintiffs lack Article III standing to challenge those future FDA rules in this case, as the government explained. Gov't Br. at 27–28 n.6. The plaintiffs do not even attempt to show how those unidentified future rules cause them an "injury in fact" that is both "concrete and

---

[6] The plaintiffs also contend that this case involves a risk of party manipulation not present in *Guedes*. Pls.' Reply at 24–25. In both cases, however, the ratifications were performed by the Presidentially-nominated and Senate-confirmed head of the defendant agency. *See Guedes*, 920 F.3d at 12.

[7] The government cited several examples of the FDA's more recent practice in which the Commissioner has signed proposed and final FDA rules. Gov't Br. at 28 n.6. The plaintiffs suggest that those examples are insufficient. Pls.' Reply at 24. But there are others. *E.g.*, 84 Fed. Reg. 32,982 (July 11, 2019) (Acting Commissioner); 84 Fed. Reg. 31,471 (July 2, 2019) (Acting Commissioner).

particularized" and "actual or imminent" — let alone how that injury would be redressed by invalidation of the deeming rule.[8] *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (citations omitted). The plaintiffs' professed desire to use "this case ... to bind FDA to the principle that rules issued by a mere employee violate the Appointments Clause, an outcome that would clearly bear on future vaping-related rules" (Pls.' Reply at 25) is an acknowledgement that what they really seek is an advisory opinion.

C. The deeming rule was issued by a duly appointed inferior officer

Finally, the government explained that, even if the Appointments Clause claim had not been forfeited or cured by ratification, it fails on the merits because Associate Commissioner Kux was a duly appointed inferior officer. Gov't Br. at 28–38.

1. The Associate Commissioner for Policy is an inferior officer

The Associate Commissioner for Policy is an inferior officer because she is subject to substantial direction, supervision, and removal by other officers nominated by the President and confirmed by the Senate. Gov't Br. at 28–35. The plaintiffs' disagreement with that proposition suffers from two main flaws.

First, the plaintiffs attack each means of control over the Associate Commissioner for Policy *in isolation*. Pls.' Reply at 10–17. But these control factors "are [not] to be weighed independently." *Estes*, 219 F. Supp. 3d at 38. Instead, courts "consider[] all of

[8] The plaintiffs attempt to establish redressability (though not injury or traceability) by virtue of their requests for declaratory relief and "any other relief that the Court determines to be just and proper." Pls.' Reply at 25. But to pursue a declaratory judgment, the plaintiffs must show "a likelihood of future violations of their rights by" the defendant — which they have not attempted to do here. *Fair Emp't Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1273 (D.C. Cir. 1994). Nor have they articulated how some other unspecified relief would give them standing.

the[] factors" together to determine whether the officer's work "is directed and supervised at some level by others" nominated by the President and confirmed by the Senate. *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1338, 1340 (D.C. Cir. 2012) (*Intercollegiate II*) (quoting *Edmond v. United States*, 520 U.S. 651, 663 (1997)).

The second and more fatal flaw in the plaintiffs' argument is that it is based almost entirely on the *current* provisions for control over the Associate Commissioner for Policy — ignoring her superiors' ability to *change* those provisions to exert more control. Pls.' Reply at 10–17. "[A] supervisor's ability to rescind provisions assuring an officer's independence can render that officer inferior," as the plaintiffs ultimately acknowledge. *In re Grand Jury Investigation*, 916 F.3d 1047, 1052 (D.C. Cir. 2019); Pls.' Reply at 17. That consideration makes logical sense because the status of the Associate Commissioner for Policy turns on all of her superiors' supervisory authority — not only their self-imposed restraints, but also their ability to lift those restraints. Here, both the HHS Secretary and the FDA Commissioner can at any time require the Associate Commissioner for Policy to obtain their approval before issuing FDA rules — or can rescind her rulemaking authority entirely.[9] FDA Staff Manual Guides

[9] The plaintiffs hypothesize that the Associate Commissioner for Policy could issue rules without advance supervisor approval. Pls.' Reply at 17. Any suggestion that she did so here, however, is at odds with the record, which shows the HHS Secretary's and FDA Commissioner's contemporaneous endorsements of the rule. APP 225–226. In any event, the current delegations of authority can at any time be changed so that either the HHS Secretary or the FDA Commissioner (or both) must approve the Associate Commissioner for Policy's rules before they can take effect, as explained above.

Regardless, the plaintiffs' contention conflates the principal-vs.-inferior officer standard with the officer-vs.-employee standard. "'Officers,' both principal and inferior, have the power to issue rules." *Alfa Int'l Seafood*, 264 F. Supp. 3d at 41. What makes the Associate Commissioner for Policy an inferior officer is that she can issue rules only

§ 1410.10(1)(A)(14) (APP 19–20); FDA Staff Manual Guides § 1410.21(1)(A) (APP 40). The same is true of every other power of the Associate Commissioner for Policy: All can be made subject to approval of the Secretary or Commissioner or taken away altogether. 42 U.S.C. § 3501 (Sec. 6); 5 U.S.C. § 302(b). This unfettered ability to rescind existing delegations of authority makes it clear that the Associate Commissioner for Policy has "no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers."[10] *Edmond*, 520 U.S. at 665.

---

because the HHS Secretary and FDA Commissioner have delegated that authority to her. *See Edmond*, 520 U.S. at 665; *see also Go-Bart Importing Co. v. United States*, 282 U.S. 344, 352–353 & n.2 (1931) (United States commissioners who could issue warrants for the arrest and detention of defendants without advance approval nonetheless "are inferior officers").

[10] Even setting aside this power to alter the provisions for control over the Associate Commissioner for Policy, the plaintiffs analyze the existing provisions under incorrect legal standards and thereby understate the extent of control. As one example, they contend that the HHS Secretary's retained authority to approve significant FDA rules is limited because the Secretary supposedly did not approve the deeming rule. Pls.' Reply at 12 & n.4. But HHS included the deeming rule as one of its own "rulemaking activities" in the unified agenda, and the HHS Secretary publicly endorsed it. APP 146, 149–150, 225. Regardless, whether a superior *in fact* exercised direction or supervision in any particular instance is irrelevant under the governing legal standard. Instead, what matters is the superior's *ability* to direct and supervise. *See Estes*, 219 F. Supp. 3d at 38; *Intercollegiate II*, 684 F.3d at 1341.

As a second example, the plaintiffs contend that the OIRA Administrator's review of significant FDA rules is not plenary. Pls.' Reply at 12–13. But the fact that the scope of control over an officer is "not complete" does not make the officer a principal officer, as the Supreme Court has held. *Edmond*, 520 U.S. at 664. Instead, what matters is that the officer "ha[s] no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Id.* at 665. Here, the deeming rule signed by Associate Commissioner Kux became a binding rule only after the OIRA Administrator reviewed it. *See* AR 28,417, 29,461–29,965.

As a third example, the plaintiffs contend that the FDA Commissioner's retained rulemaking authority is inadequate because once the Associate Commissioner for Policy has issued a final rule, the FDA Commissioner cannot change it without notice-and-comment rulemaking. Pls.' Reply at 11–12 (citing *Edmond*, 520 U.S. at 665). But "the reversibility of an official's decisions" is "less relevant" when "evaluat[ing] the status of a

The plaintiffs contend that the Associate Commissioner for Policy is nevertheless a principal officer because of the statutory civil service protections for career Senior Executive Service members. Pls.' Reply at 13–17. But like all SES positions, the Associate Commissioner for Policy can be excepted from those protections (including the for-cause removal protection) to ensure adequate control — a significant check that the plaintiffs fail to address. 5 U.S.C. §§ 2302(a)(2)(B), 3132(c), 3302, 7511(b). And even while subject to those protections, the Associate Commissioner for Policy can be reassigned to another SES position or stripped of all of her delegated powers for any reason not listed in 5 U.S.C. § 2302(b) — including failure to follow the direction of the HHS Secretary or FDA Commissioner.[11] In short, SES members' statutory civil service protections are not the kind of "significant and unusual protections from Presidential oversight" that make an official a principal officer, as the Supreme Court has recognized. *Free Enterprise Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 506–507 (2010).

Despite these considerable controls, the plaintiffs contend that the power to reassign and to strip of authority is not enough, and that only the power to completely remove an official from federal employment is sufficient for inferior officer status. Pls.'

---

policymaking official rather than an adjudicative body like those at issue in *Edmond* and *Intercollegiate*," as this Court has observed. *Estes*, 219 F. Supp. 3d at 39 n.12.

[11] The plaintiffs suggest — with no authority — that these actions would be tantamount to removal under the SES statutes and thus could be taken only for the limited grounds in 5 U.S.C. § 7543(a). Pls.' Reply at 14. Contrary to their suggestion, the actions covered by § 7543(a) are limited to "a removal from the civil service or suspension for more than 14 days." 5 U.S.C. § 7542. A reassignment to another SES position or a rescission of delegated powers within the same SES position — with no change in salary, benefits, or other civil service protections — is not a removal from civil service.

Reply at 15–17. They cite no cases holding or even suggesting as much.[12] To the contrary, *Edmond* recognized that the power to remove a judge "from his judicial *assignment*" — i.e., the particular "position or duty" to which he is "'assigned' or 'detailed,'" as opposed to his entire "appointment" to the court — was the "powerful tool for control" that supported inferior officer status. 520 U.S. at 657–658, 664 (citation omitted) (emphasis added). The powers to reassign the Associate Commissioner for Policy to another SES position and to rescind her delegated powers are similarly powerful tools for control that make her an inferior officer.[13]

In all events, even if complete removal from federal employment were what mattered, the SES statutory protections alone would not make the Associate Commissioner for Policy a principal officer. *See* 5 U.S.C. § 7543(a) (SES members may be removed "only for misconduct, neglect of duty, malfeasance, or failure to accept a directed reassignment or to accompany a position in transfer of function"). The Supreme Court "has upheld for-cause limitations on th[e] power" to remove inferior

---

[12] The authorities they cite about the general importance of "removal" (Pls.' Reply at 15) do not support their position because none suggest that the Appointments Clause requires removal *from federal employment entirely*, instead of removal *from the position in question*.

[13] If anything, the powers here are *stronger* than the reassignment power in *Edmond*. The reassignment power in *Edmond* could not remove the judge from the court, meaning he remained an officer of the United States. 520 U.S. at 664. Here, stripped of her delegated powers, the Associate Commissioner for Policy would not "exercis[e] significant authority pursuant to the laws of the United States" under the plaintiffs' theory and thus would no longer be an officer of the United States. *See Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam)).

officers. *Free Enterprise Fund*, 561 U.S. at 493 (citing *United States v. Perkins*, 116 U.S. 483 (1886), and *Morrison v. Olson*, 487 U.S. 654 (1988)).[14]

The repercussions of the plaintiffs' position, if adopted, would be extraordinary. Under their theory — which makes removal, and only removal, the relevant criterion, Pls.' Reply at 15 — it would be unconstitutional for *any* inferior officer position to be held by a career SES member, given their statutory civil service removal protections. The plaintiffs' theory would thus call into question the constitutionality of the work done by the more than 7,000 career SES members who serve "in the key positions just below the top Presidential appointees" in some 75 federal agencies — including the Defense Department, the Department of Homeland Security, and the Justice Department. *See Senior Executive Service*, Office of Personnel Management, available at https://www.opm.gov/policy-data-oversight/senior-executive-service/ (last visited July 28, 2019); *Senior Executive Service: Facts & Figures – Demographics*, Office of Personnel Management, available at https://www.opm.gov/policy-data-oversight/senior-executive-service/facts-figures/#url=Demographics (last visited July 28, 2019). The consequences to the executive branch can hardly be overstated. Under the correct standard, however, the Associate Commissioner for Policy's work "is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate," making her an inferior officer under the Appointments Clause. *See Edmond*, 520 U.S. at 663.

---

[14] Given this reaffirmation of *Perkins* by the Supreme Court as recently as 2010, the plaintiffs are wrong to suggest that *Perkins* is no longer good law. Pls.' Reply at 17; *see also Morrison*, 487 U.S. at 689 n.27 (citing *Perkins* with approval); *id.* at 724 & n.4 (Scalia, J., dissenting) (same).

2. Ms. Kux was duly appointed

The government also explained that Ms. Kux was duly appointed to the precursor position to the Associate Commissioner for Policy by the HHS Secretary, a "Head[] of Department[]" within the meaning of the Appointments Clause. Gov't Br. at 35–38. That appointment was "by Law," as it fell well with the HHS Secretary's broad statutory authority to coordinate and oversee FDA operations, 21 U.S.C. § 393(d)(2), to hire employees and appoint senior executives to SES positions, 5 U.S.C. §§ 3101, 3131, 3133, and to delegate any function to subordinates. 42 U.S.C. § 3501 (Sec. 6); 5 U.S.C. §§ 301, 302(b). Gov't Br. at 36–37.

In response, the plaintiffs do not dispute that the HHS Secretary is a department head under the Appointments Clause. Nor do they dispute that the HHS Secretary approved Ms. Kux's appointment to the position. Instead, their main response is that Congress did not empower the HHS Secretary to appoint the Associate Commissioner for Policy. Pls.' Reply at 3–7. They acknowledge, however, that the Appointments Clause does not require a statute to specifically name a particular officer. Pls.' Reply at 3–4. Yet they contend that the statute must use the word "appoint." Pls.' Reply at 4. But they cite no cases imposing that kind of strict "magic words" requirement on Congress.[15] To the contrary, such a requirement would be at odds with the "relaxed requirements for 'inferior officer' appointments." *Pa. Dep't of Pub. Welfare v. HHS*, 80 F.3d 796, 804–805 (3d Cir. 1996). Courts have thus held that even general statutes empowering

[15] Contrary to the plaintiffs' contention, the Supreme Court did not require any such magic words in *Edmond v. United States*, 520 U.S. 651 (1997). Pls.' Reply at 4. Although the statute in *Edmond* provided explicit authority to appoint the particular officers in question, "nothing in *Edmond* requires such explicit language." *Willy v. Admin. Review Bd.*, 423 F.3d 483, 493 (5th Cir. 2005).

department heads to regulate agency operations — without using the word "appoint" — satisfy the Appointments Clause.[16] *E.g.*, *Willy v. Admin. Review Bd.*, 423 F.3d 483, 491–492 (5th Cir. 2005) (holding that Appointments Clause was satisfied by statutes empowering department head to "prescribe regulations for the government of his department," 5 U.S.C. § 301, and to "authoriz[e] the performance by any other officer ... or employee ... of any function of the Secretary," 5 U.S.C. app'x 1, Reorg. Plan No. 6 of 1950, Sec. 2); *Varnadore v. Sec'y of Labor*, 141 F.3d 625, 631 (6th Cir. 1998) (similar).

The plaintiffs contend that the statutes upheld in *Willy* and *Varnadore* are different from the HHS statutes here because "[t]he Labor Department statutes ... are short, vague, and very old." Pls.' Reply at 6–7 (citing *United States v. Janssen*, 73 M.J. 221, 224 (C.A.A.F. 2014)). Even if those factors were relevant under the Appointments Clause, they would bolster — not undermine — the HHS Secretary's constitutional authority here. The statute authorizing the Labor Secretary to "prescribe regulations for the government of his department," 5 U.S.C. § 301, also gives the HHS Secretary the same authority — with no difference in statutory length, specificity, or age. And there is no material difference between the 1950 statutory reorganization plan empowering the Labor Secretary to "authoriz[e] the performance by any other officer, or by any agency or employee, of the Department of Labor of any function of the Secretary," 5 U.S.C. app'x 1, Reorg. Plan No. 6 of 1950, Sec. 2, and the 1953 statutory reorganization plan empowering the HHS Secretary to "authoriz[e] the performance of any of the functions of the Secretary by any other officer, or by any agency or employee, of the Department,"

---

[16] Even if the Appointments Clause required Congress to use the word "appoint," Congress did so here. Congress provided "authority for *appointment*" of senior executives to allotted SES positions in 5 U.S.C. § 3133 (emphasis added).

42 U.S.C. § 3501 (Sec. 6).[17] Thus, even if the *Janssen* standard applied, the statutes here are indistinguishable from the ones upheld in *Willy* and *Varnadore* — unlike the longer, more specific, and newer ones struck down in *Janssen*.

The plaintiffs also contend that reading these statutes to empower the HHS Secretary to appoint the FDA Associate Commissioner for Policy would make other statutes giving the HHS Secretary more specific appointment powers redundant. Pls.' Reply at 6. But there is no redundancy when one statute provides for the appointment of particular officers to carry out particular functions that *Congress* deems appropriate and another authorizes the appointment of other officers to carry out other functions as *the department head* deems appropriate. And regardless, the plaintiffs' claims of redundancy across different statutes enacted decades apart run afoul of the principle that, "[u]nlike two provisions within a single statute, [courts] need not construe separate statutes to avoid redundancy." *United States v. Oral George Thompson*, 921 F.3d 263, 267 & n.3 (D.C. Cir. 2019) (quoting *Bennett v. Islamic Republic of Iran*, 618 F.3d 19, 23 (D.C. Cir. 2010)). In all events, the "preference for avoiding surplusage constructions is not absolute" and would not justify wholesale invalidation of the deeming rule and the FDA's regulation of e-cigarettes as tobacco products — to say nothing of the many other FDA rules that the plaintiffs say suffer from the same defect. *Lamie v. U.S. Trustee*, 540 U.S. 526, 536 (2004).

[17] Notably, this kind of agency-specific statutory reorganization plan authorizing delegation of functions to subordinates was absent in *Janssen*. *See* 73 M.J. at 224–225 (distinguishing *Willy* because "Reorganization Plan No. 6 is specific to the Secretary of Labor and has no relevance to the Secretary of Defense").

Finally, the plaintiffs contend that the HHS Secretary's "[a]pprov[al]" (APP 229) of Ms. Kux to the position violates the Appointments Clause. Pls.' Reply at 7–10. But the Supreme Court has repeatedly "found that the department head's approval satisfies the Appointments Clause." *Free Enterprise Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 512 n.13 (2010) (citing cases); *accord United States v. Hartwell*, 73 U.S. 385, 393–394 (1867).[18] The Secretary's concurrence power for SES appointments fully satisfies the framers' desire for accountability (*see* Pls.' Reply at 8–9) because, as the government explained, it guarantees that no one becomes Associate Commissioner for Policy without the Secretary's say-so. Gov't Br. at 35–36 n.14. Here, although the FDA Commissioner "recommend[ed]" Ms. Kux for the position, it was the HHS Secretary who "[a]pproved" her appointment, APP 229, making her a duly appointed inferior officer under the Appointments Clause.

---

[18] The plaintiffs contend that *Hartwell* concerned the meaning of "officer" in a statute, not the Constitution. Pls.' Reply at 9–10. But the Supreme Court reads *Hartwell* to "have ... found that the department head's approval satisfies *the Appointments Clause*," not merely a statute. *Free Enterprise Fund*, 561 U.S. at 512 n.13 (emphasis added) (citing, inter alia, *Hartwell*, 73 U.S. at 393–394); *accord United States v. Smith*, 124 U.S. 525, 532–533 (1888) (relying on *Hartwell* in Appointments Clause analysis).

More broadly, the plaintiffs contend that even if the Appointments Clause allows appointment-by-approbation authorized by *statute*, it does not allow appointment-by-approbation authorized by *regulation*. Pls.' Reply at 9–10. But the Supreme Court has looked to both statutes and regulations in determining whether an appointment-by-approbation satisfies the Appointments Clause. *See United States v. Mouat*, 124 U.S. 303, 307–308 (1888) ("[T]here is no statute authorizing the secretary of the navy to appoint a pay-master's clerk, nor is there any act requiring his approval of such an appointment, and *the regulations of the navy do not seem to require any such appointment or approval for the holding of that position*," so the claimant "was not an officer, either appointed by the president, or under the authority of any law vesting such appointment in the head of a department.") (emphasis added).

III. Conclusion

The government's cross-motion should be granted.

Dated: August 1, 2019

Respectfully submitted,

Of counsel:

ROBERT P. CHARROW
General Counsel
U.S. Dep't of Health and Human Services

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
U.S. Dep't of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation

WENDY S. VICENTE
Senior Counsel

PETER G. DICKOS
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration

JOSEPH H. HUNT
Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

/s/ Garrett Coyle
GARRETT COYLE
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Phone: (202) 616-8016
Fax: (202) 616-8470
Email: garrett.coyle@usdoj.gov

Counsel for Defendants